UNITED STATES DISTRICT COURT
MIDDLE DISTRICT OF PENNSYLVANIA

RICHARD M. FORD and SANDY S. FORD, husband and wife Plaintiffs v. ST. JUDE MEDICAL, LLC, AND ST. JUDE MEDICAL S.C., INC., Defendants.	CIVIL ACTION NO. 3:21-CV-01765 (MEHALCHICK, J.)

MEMORANDUM

Plaintiff Richard M. Ford ("Mr. Ford") and Sandy S. Ford ("Mrs. Ford") (collectively, "the Fords" or "Plaintiffs") initiated this action by filing a complaint in the Luzerne County Court of Common Pleas against Defendants St. Jude Medical, LLC and St. Jude Medical S.C., Inc., (collectively, "Defendants"). (Doc. 1-1). On October 18, 2021, Defendants removed this case to federal court. (Doc. 1). The Fords' operative amended complaint ("Amended Complaint") asserts claims of negligence, strict liability, and breach of express and implied warranties against Defendants, as well as a claim for loss for consortium brought by Mrs. Ford related to injuries Mr. Ford suffered when his pacemaker failed. (Doc. 22). Before the Court is the Report and Recommendation (the "Report") of the Honorable Magistrate Judge Martin C. Carlson addressing a motion to dismiss the Amended Complaint filed by Defendants. (Doc. 27; Doc. 37). The Report recommends the motion to dismiss be granted in part and denied in part. (Doc. 37). The Court agrees with all the conclusions set forth in the well-reasoned Report, except for the recommendation to deny Defendants' motion to dismiss the loss of consortium claim. (Doc. 37). Accordingly, the motion to dismiss

will be **GRANTED in part** and **DENIED in part**. (Doc. 27). Plaintiffs' objections will be **OVERRULED**. (Doc. 40). Defendants' objections will be **OVERRULED in part** and **SUSTAINED in part**. (Doc. 38).

I. LEGAL STANDARDS

A. DISTRICT COURT REVIEW OF A REPORT AND RECOMMENDATION

"A district court may 'designate a magistrate judge to conduct hearings, including evidentiary hearings, and to submit to a judge of the court proposed findings of fact and recommendations for the disposition' of certain matters pending before the court." *Brown v. Astrue*, 649 F.3d 193, 195 (3d Cir. 2011) (quoting 28 U.S.C. § 636(b)(1)(B)). Within fourteen days of being served a report and recommendation, "any party may serve and file written objections to such proposed findings and recommendations as provided by rules of court." 28 U.S.C. § 636(b)(1). When a party timely files objections, the district court is to conduct a *de novo* review of the challenged portions of the Magistrate Judge's findings unless the objection is "not timely or not specific." *Goney v. Clark*, 749 F.2d 5, 6–7 (3d Cir.1984); 28 U.S.C. § 636(b)(1). The Court may then "accept, reject, or modify, in whole or in part, the findings and recommendations." 28 U.S.C. § 636(b)(1). "Although the standard is *de novo*, the extent of review is committed to the sound discretion of the district judge, and the court may rely on the recommendations of the magistrate judge to the extent it deems proper." *Rahman v. Gartley*, No. CV 3:23-363, 2024 WL 555894, at *1 (M.D. Pa. Feb. 12, 2024) (citing *United v. Raddatz*, 447 U.S. 667, 676 (1980)). For those sections of the report and recommendation to which no objection is made, the court should, as a matter of good practice, "satisfy itself that there is no clear error on the face of the record in order to accept the recommendation." Fed. R. Civ. P. Adv. Comm. Note Rule 72(b).

B. FAILURE TO STATE A CLAIM UNDER FED. R. CIV. P. 12(B)(6)

Rule 12(b)(6) of the Federal Rules of Civil Procedure authorizes a defendant to move to dismiss for "failure to state a claim upon which relief can be granted." Fed. R. Civ. P. 12(b)(6). To assess the sufficiency of a complaint on a Rule 12(b)(6) motion, a court must first take note of the elements a plaintiff must plead to state a claim, then identify mere conclusions that are not entitled to the assumption of truth, and finally determine whether the complaint's factual allegations, taken as true, could plausibly satisfy the elements of the legal claim. *Burtch v. Milberg Factors, Inc.*, 662 F.3d 212, 221 (3d Cir. 2011). In deciding a Rule 12(b)(6) motion, the court may consider the facts alleged on the face of the complaint, as well as "documents incorporated into the complaint by reference, and matters of which a court may take judicial notice." *Tellabs, Inc. v. Makor Issues & Rights, Ltd.*, 551 U.S. 308, 322 (2007).

After recognizing the required elements that make up the legal claim, a court should "begin by identifying pleadings that, because they are no more than conclusions, are not entitled to the assumption of truth." *Ashcroft v. Iqbal*, 556 U.S. 662, 679 (2009). The plaintiff must provide some factual ground for relief, which "requires more than labels and conclusions, and a formulaic recitation of the elements of a cause of action will not do." *Bell Atlantic Corp. v. Twombly*, 550 U.S. 544, 555 (2007). "[T]hreadbare recitals of the elements of a cause of action, supported by mere conclusory statements, do not suffice." *Iqbal*, 556 U.S. at 678. Thus, courts "need not credit a complaint's 'bald assertions' or 'legal conclusions'. . . " *Morse v. Lower Merion Sch. Dist.*, 132 F.3d 902, 906 (3d Cir. 1997) (quoting *In re Burlington Coat Factory Sec. Litig.*, 114 F.3d 1410, 1429-30 (3d Cir. 1997)). Nor need a court assume that a plaintiff can prove facts that the plaintiff has not alleged. *Associated Gen. Contractors of Cal. v. Cal. State Council of Carpenters*, 459 U.S. 519, 526 (1983).

A court must then determine whether the well-pleaded factual allegations give rise to a plausible claim for relief. "A claim has facial plausibility when the plaintiff pleads factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged." *Palakovic v. Wetzel*, 854 F.3d 209, 219-20 (3d Cir. 2017) (quoting *Iqbal*, 556 U.S. at 678) (internal quotation marks omitted); *see also Sheridan v. NGK Metals Corp.*, 609 F.3d 239, 262 n.27 (3d Cir. 2010). The court must accept as true all allegations in the complaint, and any reasonable inferences that can be drawn therefrom are to be construed in the light most favorable to the plaintiff. *Jordan v. Fox, Rothschild, O'Brien & Frankel*, 20 F.3d 1250, 1261 (3d Cir. 1994). This "presumption of truth attaches only to those allegations for which there is sufficient factual matter to render them plausible on their face." *Schuchardt v. President of the U.S.*, 839 F.3d 336, 347 (3d Cir. 2016) (internal quotation and citation omitted). The plausibility determination is context-specific and does not impose a heightened pleading requirement. *Schuchardt*, 839 F.3d at 347.

C. PREEMPTION AND THE MDA

The Medical Device Amendments ("MDA"), 21 U.S.C. § 360c *et seq.*, to the Food, Drug, and Cosmetic Act ("FDCA") impose federal oversight over the approval of medical devices. *See* 21 U.S.C. § 360c. The MDA applies to pacemakers as "Class III" medical devices. *Medtronic Inc., v. Lohr*, 518 U.S. 470, 477 (1995) (citing 21 C.F.R. § 870.3610 (1995)) ("Pacemakers are Class III devices"). Class III medical devices are those that are "(I)[] purported or represented to be for a use in supporting or sustaining human life or for a use which is of substantial importance in preventing impairment of human health, or (II) present[] a potential unreasonable risk of illness or injury." 21 U.S.C. § 360c. Class III medical devices must go through a premarket approval ("PMA") process in order to assure safety and

effectiveness. *See* 21 U.S.C. § 360c. After the PMA, manufacturers cannot "make, without FDA permission, changes in design specifications, manufacturing processes, labeling, or any other attribute, that would affect safety or effectiveness." *Riegel v. Medtronic, Inc.*, 552 U.S. 312, 319 (2008) (citing 21 U.S.C. § 360e(d)(6)(A)(i)).

The MDA also contains a preemption provision. 21 U.S.C. § 360k(a). According to the preemption provision, state tort claims against medical manufacturers are barred when such claims implicate requirements that are different from or additional to the federal standards. *See Conley v. St. Jude Medical, LLC*, 482 F. Supp. 3d 268, 275 (M.D. Pa. 2020) (the MDA bars state tort claims "insofar as such claims would impose requirements 'different from, or in addition to the requirements imposed by federal law.'") (quoting *Riegel*, 552 U.S. at 330).

The preemption provision includes an exception that allows for "parallel" state tort claims – that is, claims based upon state requirements that are parallel to, rather than additional to, federal requirements. *See Gross v. Stryker Corp.*, 858 F. Supp. 2d 466, 492 (W.D. Pa. 2012) ("In *Riegel*, the Supreme Court found that '[21 U.S.C.] § 360k does not prevent a State from providing a damages remedy for claims premised on a violation of FDA regulations' because the state duties would parallel, rather than add to, federal requirements.'") (quoting *Riegel*, 552 U.S. at 330). "To properly allege parallel claims, the complaint must set forth facts showing 'action or inaction in [defendants'] efforts to take part in the [premarket approval ("PMA") process] process or implement its results.'" *Gross*, 858 F. Supp. 2d at 492 (quoting *Parker v. Stryker Corp.*, 584 F. Supp. 2d 1298, 1301 (D. Colo. 2008). Parallel claims require a high degree of specificity about what actions or inactions by a defendant violated federal law. *See Gross*, 858 F. Supp. 2d at 493 (finding that the parallel

claims exception is inapplicable when "(1) [p]laintiff fails to adequately plead a sufficient, *specific* basis for his purported parallel claims, and (2) [p]laintiff's claims arise from generalized common theories of liability and not state statutes that provide a private cause of action for FDCA violations") (emphasis added). However, when plaintiffs fail to allege facts with such required specificity, leave to amend may be appropriate. *See Freed v. St. Jude Med., Inc.*, No. CV 17-1128, 2017 WL 4102583, at *8 (D. Del. Sept. 15, 2017) ("[t]he [plaintiffs] do not presently allege facts necessary to overcome federal preemption[. . . ,]" but noting "[t]hey may be able to do so with an amendment.").

D. COMMENT K

Pennsylvania has adopted the Restatement (Second) of Torts, which includes § 402 Comment k ("Comment k"). *See* Restatement (Second) of Torts § 402A cmt. k (1965). "Comment k of Section 402A, [] limits liability for 'unavoidably unsafe' products." *Kline v. Zimmer Holdings, Inc.*, No. CIV.A. 13-513, 2013 WL 3279797, at *4 (W.D. Pa. June 27, 2013); s*ee also Hahn v. Richter*, 673 A.2d 888, 889 (Pa. 1996). Comment k limits liability for such products because "[t]here are some products, which, in the present state of human knowledge, are quite incapable of being made safe for their intended and ordinary use," but that when "properly prepared, and accompanied by proper directions and warning, [the product] is not defective, nor is it *unreasonably* dangerous." Restatement (Second) of Torts § 402A cmt. K; *see Kline*, 2013 WL 3279797, at *4. The Pennsylvania Supreme Court has explicitly held that Comment k applies to prescription drugs and the Pennsylvania Superior Court has extended Comment k to medical devices, noting that there is "no reason why the same rational[e] applicable to prescription drugs may not be applied to medical devices." *see Kline*, 2013 WL 3279797, at *4 (quoting *Creazzo v. Medtronic, Inc.*, 903 A.2d 24, 31 (Pa. Super. Ct. 2006)). A

growing body of district courts in the Third Circuit have predicted that the Pennsylvania Supreme Court will extend Comment k's bar on strict liability claims to medical devices as well. *See Gross*, 858 F. Supp. 2d at 482 ("Most importantly, courts within the Third Circuit have barred strict liability claims against [defendant] and other analogous medical device manufacturers by applying comment k to § 402A."); *McGrain v. C.R. Bard, Inc.*, 551 F. Supp. 3d 529, 537 (E.D. Pa. 2021) ("many federal courts, including this one, have predicted that the Pennsylvania Supreme Court would extend Comment k to medical devices.") (citing *Lopez v. Ethicon Inc.,* No. CV 20-2694, 2020 WL 5569770, at *5 (E.D. Pa. Sept. 17, 2020); *Cf. Ebert v. C.R. Bard, Inc.*, 459 F. Supp. 3d 637, 652–53 (E.D. Pa. 2020) (predicting that "Pennsylvania's highest court [will]. . . analyze comment k's applicability to prescription medical devices on a case-by-case basis, determined largely by each case's developed factual record and the individual characteristics of the medical device at issue").

District courts in Pennsylvania have also discussed Comment k regarding a breach of implied warranties claim and note that these implied warranties claims fail for the same reason as the strict liability claims. *McDonnell v. Flowonix Med. Inc.*, No. CV 21-1404, 2022 WL 221612, at *7 (E.D. Pa. Jan. 25, 2022) ("Courts in this Circuit, relying on *Makripodis*, have concluded that Comment k is equally applicable to strict liability and breach of implied warranty.") (citing *Terrell v. Davol, Inc.*, No. 13-5074, 2014 WL 3746532, *6 (E.D. Pa. July 30, 2014); *See, e.g., Gross*, 858 F. Supp. 2d at 491 n.35; *Soufflas v. Zimmer, Inc.*, 474 F. Supp. 2d 737, 752 (E.D. Pa. 2007)); *Cogswell v. Wright Med. Tech., Inc.*, No. 15-295, 2015 WL 4393385, at *5 (W.D. Pa. July 16, 2015) (holding that Comment k bars implied warranties claims and stating "[a] number of Pennsylvania federal courts have extended [Comment k's] reasoning to preclude implied warranty of fitness and merchantability claims for medical devices as

well."); *Kester v. Zimmer Holdings, Inc.*, No. 210-CV-00523, 2010 WL 2696467, at *11 (W.D. Pa. June 16, 2010) ("As with strict products liability claims [. . .], Pennsylvania courts have held that the nature of prescription drugs *and* prescription medical devices precludes claims for breach of implied warranty") (citing *Parkinson v. Guidant Corp.,* 315 F. Supp. 2d 741, 753 (W.D. Pa. 2004)); *Carson v. Atrium Med. Corp.*, 191 F. Supp. 3d 473, 478 (W.D. Pa. 2016) (dismissing a breach of an implied warranties claim as materially similar to the strict liability claim and stating "since this Court has determined, both in this case and in previous cases, that medical devices fall under the umbrella of Comment k, and thus are unavoidably unsafe products, there can be no breach of implied warranty"); *Horsmon v. Zimmer Holdings, Inc.*, No. CIV.A. 11-1050, 2011 WL 5509420, at *3 (W.D. Pa. Nov. 10, 2011) (dismissing a breach of an implied warranty claim "[b]ecause Pennsylvania law precludes breach of implied warranty claims for medical devices" through Comment k).

II. DISCUSSION

Since the Report explains the factual and procedural background of this case in detail, this Court will only include here what is relevant for the purposes of this Memorandum.[1] This case arises from injuries Mr. Ford suffered when he fell due to a pacemaker failure. (Doc. 22, ¶ 24). Plaintiffs' operative Amended Complaint asserts claims against Defendants for strict liability, negligence, breach of implied and express warranties, and loss of consortium. (Doc. 22). The Report concludes that Plaintiffs' negligence, strict liability, and breach of implied warranties claims fail because they are preempted by federal law. (Doc. 37, at 10). However,

[1] Pennsylvania law applies to the tort and contract claims in this case, so the Court will rely on both state law and federal application of state law. *See Kline v. Zimmer Holdings, Inc.*, 662 F. App'x 121 (3d Cir. 2016) (applying state law to medical products liability claims for negligence, design and manufacturing defects, and loss of consortium).

according to the Report, Plaintiffs' breach of express warranties claim should survive because it is not preempted by federal law and Plaintiffs have adequately stated a claim under Pennsylvania law. (Doc. 37, at 10). Magistrate Judge Carlson recommends the loss of consortium claim also survives as a derivative claim to the breach of express warranties claim. (Doc. 37, at 24). The parties each filed objections to the Report. (Doc. 38; Doc. 39; Doc. 40).

Defendants object to the Report with respect to two discrete issues. (Doc. 38, at 5). First, Defendants submit that the breach of implied warranties claim should be dismissed with prejudice, rather than without prejudice. (Doc. 38, at 5). Second, Defendants contend that loss of consortium claim should be dismissed without prejudice because the only surviving claim, the breach of express warranties claim, cannot support a derivative loss of consortium claim. (Doc. 38, at 5). Plaintiffs object to the Report's recommendation in one respect, arguing that Comment k does not bar their strict liability claims and contending that their strict liability claims should be dismissed *without* prejudice and that they be granted an opportunity to file a second amended complaint. (Doc. 40, at 20).

A. PLAINTIFFS' STRICT LIABILITY CLAIMS

According to the Report, Plaintiffs' strict liability claims should be dismissed with prejudice because (1) they are preempted by federal law and (2) "many courts within this circuit have predicted that the Pennsylvania Supreme Court would extend the exemption provided in [C]omment k to strict liability claims sounding in design defect and manufacturing defect against manufacturers of medical devices." (Doc. 37, at 16). In recommending dismissal of the strict liability claims, the Report found persuasive several Third Circuit district courts applying Comment k to medical devices and barring strict liability claims for manufacturing and design defects against manufacturers. (Doc. 37, at 16) (citing

McGrain, 551 F. Supp. 3d at 537; *Rosenberg v. C.R. Bard, Inc.*, 387 F. Supp. 3d 572, 579-81 (E.D. Pa. 2019); *Wilson v. Synthes USA Prods., LLC*, 116 F. Supp. 3d 463, 465-67 (E.D. Pa. 2015); *Gross*, 858 F. Supp. 2d at 482).

Plaintiffs do not object to the dismissal on preemption grounds, but instead object to the dismissal *with prejudice*, arguing that Comment k does not apply to strict liability manufacturing or design defect claims and that they could feasibly state a parallel claim if granted leave to amend. (Doc. 40, at 12). First, Plaintiffs assert that Comment k preserves manufacturing defect claims because "Comment k insulates sellers from strict liability for [only those] products that are 'properly prepared.'" (Doc. 40, at 13). Plaintiffs cite a previous opinion by this Court in *Wallace v. Boston Scientific Corp.*, which denied a motion to dismiss a strict liability claim based upon a manufacturing defect. (Doc. 40, at 13); *see* No. 3:18-CV-01839, 2018 WL 6981220, at *6 (M.D. Pa. Nov. 29, 2018), *report and recommendation adopted,* No. 3:18-CV-1839, 2019 WL 137605 (M.D. Pa. Jan. 8, 2019). The *Wallace* Court recommended denying the motion to dismiss because "the Pennsylvania Supreme Court has had ample opportunity to preclude manufacturing defect claims and has not yet done so," suggesting that Comment k does not preclude such claims. (Doc. 40, at 13). Second, Plaintiffs contend that Comment k also does not apply to design defect claims. (Doc. 40, at 13). However, Plaintiffs fail to address the Report's conclusion that design defect claims are barred by Comment k with any degree of specificity. (Doc. 40, at 13). Instead, they repeat their argument that manufacturing defect claims are not necessarily barred by Comment k and assert that the application of Comment k to strict liability design defect claims is at odds with three cases in this district: *Goodling v. Johnson & Johnson*, 2022 WL 414285 (M.D. Pa. 2022); *Russell v. Ethicon Inc.*, 2020 WL 5993774 (M.D. Pa. 2020); and *Patchcoski v. WL. Gore &*

Associates, Inc., 2020 WL 4335016 (M.D. Pa. 2020). Notably, the three cases that Plaintiffs cite for its contention that Comment k does not bar strict liability design defect claims do not claim that the Pennsylvania Supreme Court has yet ruled on Comment k's application to such claims one way or the other. *See, e.g.*, *Goodling*, 2022 WL 414285, at *4; *Russell*, 2020 WL 5993774, at *7; *Patchcoski*, 2020 WL 4335016, at *7.

Plaintiffs do not explain in any detailed manner why this Court should break from the many other courts in this Circuit, discussed *supra*, that have come to the opposite conclusion and extended Comment k to bar all strict liability claims, including those for manufacturing and design defects in medical devices. (Doc. 40); *see Kohn v. Ethicon, Inc.*, 2020 WL 733126, at *4 (E.D. Pa. Feb. 13, 2020) (predicting that Pennsylvania law would bar strict liability claims in medical device cases and citing to other cases predicting the same); *Rosenberg*, 387 F. Supp. 3d at 576–81. In opposition, Defendants maintain that Comment k does apply to medical devices, suggesting that the body of law dismissing such claims is large, robust, and recent. (Doc. 42, at 6). They point out that several district courts in this Circuit have, as recently as 2022, applied Comment k to medical devices and dismissed strict liability claims on that basis. (Doc. 42, at 6-7).

Plaintiff's objections as they relate to the strict liability claims will be overruled. First, as the Report correctly concludes, many district courts in this Circuit have applied Comment k to medical devices to bar all strict liability claims. *McGrain*, 551 F. Supp. 3d at 537; *Rosenberg*, 387 F. Supp. 3d at 577-81 ("comment k's plain language appears to include prescription medical devices because 'prescription' medical devices, by definition, are products that require a physician's prescription, just as 'prescription' drugs also, by definition, require a physician's prescription"); *Wilson*, 116 F. Supp. 3d at 465-67 (finding that Comment

k applies to medical devices and stating "I find this attempt to distinguish medical devices from prescription drugs to be unpersuasive, as both medical devices AND prescription drugs could be manufactured in different ways to make them more fit for their purpose."); *Gross*, 858 F. Supp. 2d at 482 (holding that Comment k applies to medical device strict liability claims). The Court agrees with the Report that the reasoning in such cases is persuasive. *See Rosenberg*, 387 F. Supp. 3d at 579-81 (barring strict liability claims for medical devices because both case law and Comment k's plain language support doing so); *McGrain*, 551 F. Supp. 3d at 537 ("In the absence of further guidance from the Pennsylvania Supreme Court[. . .], this [c]ourt predicts, as have other courts, that the Pennsylvania Supreme Court would preclude strict liability manufacturing defect claims against medical device manufacturers"). Accordingly, this Court agrees with the Report's reasoning and conclusion that Comment k applies to all strict liability claims, including those for medical devices. (Doc. 37, at 18). This Court will therefore adopt the Report's recommendation that the strict liability claims be dismissed with prejudice. (Doc. 37, at 18). Defendants motion to dismiss Plaintiffs' strict liability claims is **GRANTED**. (Doc. 27); *see McGrain*, 551 F. Supp. 3d at 537. Count III is **DISMISSED**. (Doc. 22).

A. PLAINTIFFS' BREACH OF IMPLIED WARRANTIES CLAIM

The Report recommends that Plaintiffs' breach of implied warranties claim be dismissed because such claims are preempted by federal law. (Doc. 37, at 25). According to the Report, and as noted *supra*, the MDA imposes federal oversight over the approval of medical devices including pacemakers and bars state tort claims when "such claims would impose requirements different from, or in addition to the requirements imposed by federal law." (Doc. 37, at 11-12) (quoting *Conley*, 482 F. Supp. 3d at 275 (internal quotations

omitted)) (citing 21 U.S.C. § 360c(C)). The Report provides that Pennsylvania law imposes its own standards on medical devices which are different or in addition to the federal standards, through its adoption of the "Uniform Commercial Code formulations of the implied warranty of fitness for a particular purpose and the implied warranty of merchantability." (Doc. 37, at 21) (quoting *Bentzley*, 827 F. Supp. 2d at 454); *see also* 13 Pa. Cons. Stat. §§ 2314, 2315). The Report concludes that allowing a breach of implied warranties claim based upon the different or additional Pennsylvania standards would violate the preemption provision of the MDA. (Doc. 37, at 21). This Court agrees.

Defendants object to the Report's apparent recommendation that the breach of implied warranties claim be dismissed *without* prejudice, arguing that the claim should be dismissed *with* prejudice.[2] (Doc. 38, at 5). Defendants submit that the breach of implied warranties claim falls within "the purview of Restatement (Second) of Torts, § 402A Comment k," which bars certain causes of action against manufacturers of medical devices. (Doc. 38, at 6); *see Henneman v. Zimmer Holdings, Inc.*, 2012 WL 3528004, at *1 (M.D. Pa. July 11, 2012). Plaintiffs respond that some courts in the Third Circuit, including this Court in one case, have

[2] Although in discussing the breach of implied warranties claims, the Report concludes that: "Given that Pennsylvania law imposes its own standards, allowing a breach of implied warranties claim involving a medical device that is subject to federal requirements would impose standards that are different from, or in addition to, the federal requirements. Accordingly, such claims are also expressly preempted by the MDA, and this claim should be dismissed *with* prejudice." (Doc. 37, at 21) (emphasis added), in the final Recommendation section, the Report states: "The motion should be GRANTED with respect to the breach of implied warranties claim in Count III, and this claim should be dismissed *without* prejudice to allow one final opportunity to amend the complaint." (Doc. 37, at 25) (emphasis added). This Court agrees with Magistrate Judge Carlson's conclusion in the Discussion section that the breach of implied warranties claim be dismissed *with* prejudice, but in the interest of thoroughness and treatment of all arguments by the parties, will will consider Defendants' objections to dismissal without prejudice.

"concluded that Comment k does not preclude a manufacturing defect claim." (Doc. 41, at 5). Therefore, Plaintiffs contend, because their "breach of implied warranty claim is based in part upon [their] manufacturing defect claim," the breach of implied warranty claim should also not be subject to Comment k. (Doc. 41, at 5). Thus, Plaintiffs argue that their breach of implied warranties claim should not be dismissed with prejudice. (Doc. 41, at 5). It is worth noting that again, Plaintiffs do not dispute that this claim is preempted. (Doc. 41).

Also discussed *supra*, the MDA governs federal medical device regulations, including pacemakers, and preempts any claim against a manufacturer based upon different or additional state standards. *See* 21 U.S.C. § 360. Pennsylvania has adopted the Uniform Commercial Code formulations of the implied warranty of fitness for a particular purpose and the implied warranty of merchantability. *Bentzley*, 827 F. Supp. 2d at 454 (citing 13 Pa. Cons. Stat. §§ 2314, 2315; *Borden, Inc. v. Advent Ink Co.*, 701 A.2d 255 (Pa. Super. Ct. 1997). In Pennsylvania, a breach of implied warranty claim is based on state standards. *Bentzley*, 827 F. Supp. 2d at 454 ("[i]mplied warranties in Pennsylvania are 'centered around the accepted standards of design and manufacture of products in the state of Pennsylvania.'") (quoting *Davenport v. Medtronic, Inc.*, 302 F. Supp. 2d 419, 434 (E.D. Pa. 2004); *see also* 13 Pa. Cons. Stat. §§ 2314, 2315. These standards are different than the federal standards. *See Gross*, 858 F. Supp. 2d at 490 ("it is evident that Pennsylvania state law imposes its own standards on the merchantability of goods."). Therefore, because Plaintiffs' breach of implied warranties claim is based upon state standards that are different from or additional to federal standards, this claim is preempted by the MDA. *See Gross*, 858 F. Supp. 2d at 500-01 (dismissing breach of implied warranties claim because Pennsylvania imposes requirements that are additional to federal requirements for medical devices). This Court agrees with the Report's

recommendation that this claim should be dismissed. (Doc. 37, at 21). Accordingly, Defendants' motion to dismiss the breach of implied warranties claim is **GRANTED**. (Doc. 27); *see Gross*, 858 F. Supp. 2d at 500-01. Plaintiffs' breach of implied warranties claim is **DISMISSED with prejudice**. (Doc. 22).[3]

B. NEGLIGENCE AND BREACH OF EXPRESS WARRANTIES CLAIMS

The parties do not object to the Report's recommendations that (1) the motion be granted with respect to the negligence claim and the negligence claim be dismissed without prejudice and (2) the motion be denied as to the breach of express warranties claim. (Doc. 37, at 25; Doc. 38; Doc. 40). After reviewing the relevant filings, the Court finds no error in Magistrate Judge Carlson's conclusion that the negligence claim should be dismissed without prejudice and that motion to dismiss be denied as to the breach of express warranties claim. (Doc. 37, at 18-20, 22-25). The Court finds Magistrate Judge Carlson's analysis to be well-reasoned and supported by the applicable law. (Doc. 37, at 18-20, 22-25). Accordingly, the Report's recommendations (1) that Defendants' motion to dismiss be granted with respect to the negligence claim and (2) that Defendants' motion to dismiss be denied as to the breach of express warranties claim is adopted. (Doc. 37, at 25). Defendants' motion to dismiss the negligence claim is **GRANTED**. (Doc. 27). Plaintiffs' negligence claim is **DISMISSED**

[3] As discussed *supra* in the Comment k legal standard section, Comment k likely applies to implied warranties claims for medical device defects. As such, this claim is also barred by Comment k for the same reasons that the strict liability claim is barred by Comment k. *See McDonnell*, 2022 WL 221612, at *7 (finding that Comment k bars implied warranties claims for medical device defects) (citing *Terrell*, 2014 WL 3746532, *6); *Gross*, 858 F. Supp. 2d at 491 n.35 (same); *Soufflas*, 474 F. Supp. 2d at 752 (same); *Cogswell*, 2015 WL 4393385, at *5 (same); *Kester*, 2010 WL 2696467, at *11 (same).

without prejudice. (Doc. 22). Defendants' motion to dismiss the express warranties claim is **DENIED**. (Doc. 27).

C. LOSS OF CONSORTIUM DERIVATIVE CLAIM

According to the Report, Defendants' motion to dismiss Plaintiffs' loss of consortium claim should be denied. (Doc. 37, at 24-25). The Report reasons that the loss of consortium claim attaches as a valid derivative to the surviving breach of express warranties claim. (Doc. 37, at 24). Defendants' object to the denial of their motion to dismiss Mrs. Ford's loss of consortium claim. (Doc. 38, at 7). Defendants submit that a loss of consortium claim survives only as a derivative claim, meaning "when the claims of the injured party fail, so too must the consortium claim of the spouse." (Doc. 38, at 7). Defendants further argue that because Plaintiffs' only surviving claim is the breach of express warranties claim, which Defendants contend sounds in contract, the loss of consortium claim must be dismissed. (Doc. 38, at 7).

A loss of consortium claim is a derivative claim, meaning its validity is based upon the availability of recovery for another claim. *See Kline v. Zimmer Holdings, Inc.*, 662 F. App'x 121, 121 n.1 (3d Cir. 2016) (dismissing a loss of consortium claim without a separate analysis when all other claims failed because a loss of consortium claim is derivative). Typically, a loss of consortium claim must attach to a valid tort claim. *See Harris v. Oz Directional Drilling, Inc.*, No. 3:13-CV-2580, 2016 WL 4578150, at *5 (M.D. Pa. June 30, 2016), *report and recommendation adopted*, No. 3:13-CV-2580, 2016 WL 4698635 (M.D. Pa. July 19, 2016) ("it is well-settled that: '[a] spouse's consortium claim derives only from the injured spouse's right to recover [under state law] in tort.'") (quoting *Quitmeyer v. Se. Pennsylvania Transp. Auth. ("SEPTA")*, 740 F. Supp. 363, 370 (E.D. Pa. 1990)); *see also Thomas v. Shutika*, No. 4:12-CV-692, 2012 WL 4050005, at *3 (M.D. Pa. Aug. 24, 2012), *report and recommendation adopted*,

No. 4:12-CV-692, 2012 WL 4050021 (M.D. Pa. Sept. 13, 2012) ("The defendants' praecipe [sic] to withdraw this motion to dismiss correctly acknowledges the viability of this derivative state law tort loss of consortium claim in this case"). However, in limited circumstances a loss of consortium claim can derive from a contract claim. *See Pastin v. Allstate Ins. Co.*, No. 2:17CV1503, 2018 WL 10229728, at *4 (W.D. Pa. Aug. 17, 2018) ("Under Pennsylvania law, a loss of consortium claim can be a derivative claim of a breach of contract claim."). For a loss of consortium claim to attach to a contract claim, the spouse asserting the loss of consortium claim must be a party to the same contract from which the loss of consortium claim derives. *See Perloff v. Transamerica Life Ins. Co.*, 393 F. Supp. 3d 404, 411–12 (E.D. Pa. 2019) (holding that a loss of consortium claim can attach to a contract claim and stating "although the breach of contract claim survives, a loss of consortium claim may only be based on a breach of contract where the spouse asserting loss of consortium is a party to the contract."); see also *Pastin*, 2018 WL 10229728, at *4 (allowing a loss of consortium claim to proceed based upon a contract claim when the asserting spouse was party to the insurance contract upon which the claim was based).

Here, Mrs. Ford does not allege that she was a party to the contract upon which Mr. Ford's breach of express warranties claim is based, and in the Amended Complaint, only Mr. Ford asserts the breach of express warranties claim. (Doc. 22, at 30-35). Further, Plaintiffs aver that Defendants made representations about the pacemaker's safety and effectiveness "to Richard M. Ford" and that these representations and warranties "were relied by [] Richard M. Ford when the product was used for its intended purposes." (Doc. 22, ¶¶ 82, 85). Nowhere in the Amended Complaint do Plaintiffs allege that Mrs. Ford also relied upon the express warranties. (Doc. 22, at 30-35). As such, the undersigned will not adopt the Report's

recommendation to deny the motion to dismiss the loss of consortium claim. Accordingly, the loss of consortium claim is **DISMISSED without prejudice**. *See Yauger v. Mid-Century Ins. Co.*, No. CV 23-4075-KSM, 2024 WL 555883, at *5 (E.D. Pa. Feb. 12, 2024) (dismissing a loss of consortium claim without prejudice when it was not clear whether the spouse asserting the derivative claim was party to the contract from which the loss of consortium claim derived).

III. CONCLUSION

The Court has reviewed the Report and Recommendation of Magistrate Judge Carlson and agrees with its well-reasoned conclusions in all respects except for the loss of consortium claim. (Doc. 37). Plaintiffs' objections to the Report are **OVERRULED**. (Doc. 40). Defendants' objection that the loss of consortium claim be dismissed without prejudice is **SUSTAINED**. (Doc. 38). Defendants' motion to dismiss is **GRANTED in part** with respect to the strict liability, breach of implied warranties, negligence, and loss of consortium claims in Counts I, II, III, and IV. (Doc. 27). Defendants' motion to dismiss is **DENIED in part** with respect to the breach of express warranties claim in Count III. (Doc. 27). Plaintiffs' strict liability and breach of implied warranties claims are **DISMISSED with prejudice**. (Doc. 22). Plaintiffs' negligence and loss of consortium claims are **DISMISSED without prejudice**. (Doc. 22). An appropriate Order follows.

BY THE COURT:

Date: September 23, 2024

s/ Karoline Mehalchick

KAROLINE MEHALCHICK
United States District Judge